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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,528	10/13/2000	David M. Stern	0575/62096/JPW/JML	8939

7590

06/20/2003

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EXAMINER

CHEN, SHIN LIN

ART UNIT

PAPER NUMBER

1632

13

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/687,528

Applicant(s)

Stern et al.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Apr 25, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: There is no antecedent basis for the phrase "the inhibitor" in claims 11, 13 and 14.

3. ☒ Applicant's reply has overcome the following rejection(s):
112 second paragraph rejection of claim 6, 112 first paragraph written description rejection, and 112 first paragraph new matter rejection of claim 9.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
Applicants argue that examiner indicates prevention of exaggerated restenosis in a diabetic subject with sRAGE is enabled in the Official action mailed 4-10-02 (Paper No. 8). Applicants further argue that Zucker fatty rat
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: None
- Claim(s) objected to: None
- Claim(s) rejected: 3-6, 9, and 11-14
- Claim(s) withdrawn from consideration: None
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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DETAILED ACTION

Continued from Advisory Action:

is a model of insulin resistance, hyperglycemia, hyperlipidemia and obesity, and experimental data of said Zucker fatty rats would be expected to correlate with human results (amendment, p. 5-7). This is not found persuasive because of the reasons of record. The statements on page 6 and 7 of Official action mailed 4-10-02 (Paper No. 8) meant the specification only enables reduction of smooth muscle proliferation and migration in carotid artery by treating Fatty Zucker rat with soluble RAGE (sRAGE) via intraperitoneal injection but the specification does not enable prevention of exaggerated restenosis in a diabetic subject by using any polypeptide inhibitor of RAGE. This is evident in the statement of the first paragraph of page 5 of the Official action mailed 4-10-02 (Paper No. 8), which states the specification, while being enabling for reduction of smooth muscle proliferation and migration in carotid artery by treating Fatty Zucker rat with soluble RAGE (sRAGE) via intraperitoneal injection, does not reasonably provide enablement for any method for inhibiting new tissue growth or neointimal formation in blood vessels in a subject or preventing exaggerated restenosis in a diabetic subject by administering to said subject any polypeptide inhibitor of RAGE *in vivo*. Since the specification does not enable preventing exaggerated restenosis in any diabetic subject by using any polypeptide inhibitor of RAGE, including sRAGE, *in vivo*, the specification also does not enable

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preventing exaggerated restenosis in a human *in vivo*. Thus, claims 3-6, 9 and 11-14 remain rejected under 35 U.S.C. 112 first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Shin-Lin Chen, Ph.D.